

# FRANKLIN INDUSTRIAL MINERALS



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March 31, 2000

HEADQUARTERS  
612 TENTH AVENUE, NORTH  
NASHVILLE, TENNESSEE 37203  
615-259-4222

Dockets Management Branch (HFA-305)  
Room 1061  
U.S. Food & Drug Administration  
5630 Fishers Lane  
Rockville, Maryland 20852

Dear Sir or Madam:

RE: Docket No. 99D-4201 (Dioxin in Mined Clay Used in Animal Feeds)

On October 15, 1999, FDA announced the availability of a guidance document on "Dioxin in Anti-caking Agents Used in Animal Feed and Feed Ingredients (October 6, 1999)" (64 *Fed. Reg.* 55948). The guidance was issued immediately without prior public comment. Franklin Industrial Minerals is commenting because the guidance includes references to testing which we believe to be in error.

At the time the document was issued contact was made with both Ms. Judy A. Gushee and Dr. Randall A. Lovell, Center for Veterinary Medicine, USFDA as referenced in the docket. Concerns were expressed relative to sample contamination which may have occurred. Franklin Industrial Minerals was advised to have new samples taken and to have these materials tested independently and to then submit the results with comment on the guidance document. The independent tests have been completed, summary results are attached and are included to be incorporated in the record.

## Independent Testing

Three samples of limestone, similar to the sample obtained at Bunge Corporation, Decatur, Alabama, were submitted to Triangle Laboratories, Inc., Durham, NC. The samples were tested, per EPA Method 1613, for all seventeen (17) dioxin and furan compounds referenced in the guidance document. As noted in the attached laboratory test results all compounds in all three samples recorded "not detectable", and no evidence of the presence or occurrence of dioxins or furans was found.

As was discussed with FDA's Mr. Lovell and Ms. Gushee in October, the finding of detectable dioxins in FDA Sample Number 37950 is highly suspect. This sample of limestone was

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selected from an area which had recently been used to store ball clay which could have easily contaminated the limestone. The levels found in the limestone sample (0.43 ppt TEQ) were the lowest positive results reported for any of the samples in the program. Franklin Industrial Minerals believes that this low level of detection is consistent with contamination which could have occurred in an area used to store both ball clay and limestone.

### **Limestone Is Not A Clay**

Limestone is a rock and is neither a clay or clay product (ref. *Sedimentary Rocks*, 2nd edition, by F.J. Pettijohn, John Hopkins University, Harper & Brothers, New York) High calcium limestone, as mined by Franklin Industrial Minerals, is mined from an underground mine and does not come into contact with any clay materials either in the mine or on the outside ground surface. The limestone is processed for sale in a closed loop system, and is stored in totally enclosed silos prior to shipping. Therefore, given the purity of (i.e. high calcium levels) Franklin Industrial Minerals products and the manner in which they are mined and processed the only way in which they could pick-up dioxins would be through contamination with clay materials either in transit or at the user location.

### **FDA's Guidance**

Based upon the evidence at hand, including the enclosed test results Franklin Industrial Minerals respectfully requests the following:

1. Request that FDA delete and remove all reference to FDA Sample Number 37950 and related test results from the test data accumulated during the investigation of the occurrence of dioxins in ball clay.
2. Request that FDA should rescind or modify the guidance document immediately, to delete any suggestion that "lime" or "limestone" has been found to contain dioxin. The result of such correction will be a more accurate evaluation of potential threats to public health from mined clay products.

Respectfully,



Robert C. Freas  
Vice President, Marketing

# Franklin Industrial Minerals

TLI Project: **50599**  
 Client Sample: **80616A**

1613, Revision B PCDD/PCDF Analysis (c)  
 Analysis File: **U043610**

Client Project:	<b>Dioxin In Powdered Limestone</b>		
Sample Matrix:	<b>SOLID</b>	Date Received:	<b>03/10/2000</b>
TLI ID:	<b>257-15-1</b>	Date Extracted:	<b>03/11/2000</b>
		Date Analyzed:	<b>03/16/1900</b>
		Spike File:	<b>SP161B2S</b>
		ICal:	<b>UF5831B</b>
		ConCal:	<b>UB00434</b>
Sample Size:	<b>10.000 g</b>	Dilution Factor:	<b>n/a</b>
Dry Weight:	<b>9.990 g</b>	Blank File:	<b>U043609</b>
GC Column:	<b>DB-5</b>	Analyst:	<b>BWL</b>
		% Moisture:	<b>0.1</b>
		% Lipid:	<b>n/a</b>
		% Solids:	<b>99.9</b>

Analytes	Conc. (ng/kg)	DL	Ratio	RT	RRT	Flags
2,3,7,8-TCDD	ND	0.2				---
1,2,3,7,8-PeCDD	ND	0.3				---
1,2,3,4,7,8-HxCDD	ND	0.5				---
1,2,3,6,7,8-HxCDD	ND	0.4				---
1,2,3,7,8,9-HxCDD	ND	0.4				---
1,2,3,4,6,7,8-HpCDD	ND	1.1				---
1,2,3,4,6,7,8,9-OCDD	ND	3.4				---
2,3,7,8-TCDF	ND	0.1				---
1,2,3,7,8-PeCDF	ND	0.2				---
2,3,4,7,8-PeCDF	ND	0.2				---
1,2,3,4,7,8-HxCDF	ND	0.3				---
1,2,3,6,7,8-HxCDF	ND	0.2				---
2,3,4,6,7,8-HxCDF	ND	0.3				---
1,2,3,7,8,9-HxCDF	ND	0.6				---
1,2,3,4,6,7,8-HpCDF	ND	0.6				---
1,2,3,4,7,8,9-HpCDF	ND	1.4				---
1,2,3,4,6,7,8,9-OCDF	ND	2.9				---

Totals	Conc. (ng/kg)	Number	DL	Flags
Total TCDD	ND	0.2		---
Total PeCDD	ND	0.3		---
Total HxCDD	ND	0.4		---
Total HpCDD	ND	1.1		---
Total TCDF	ND	0.1		---
Total PeCDF	ND	0.2		---
Total HxCDF	ND	0.3		---
Total HpCDF	ND	0.8		---

# Franklin Industrial Minerals

TLI Project: **50114r3**  
 Client Sample: **50616H**

1613, Revision B PCDD/PCDF Analysis (c)  
 Analysis File: **T000758**

Client Project:	<b>Dioxin In Powdered Limestone</b>			Spike File:	<b>SP161B2S</b>
Sample Matrix:	<b>SOLID</b>	Date Received:	<b>12/10/99</b>	ICal:	<b>TF5911B</b>
TLI ID:	<b>252-25-1</b>	Date Extracted:	<b>02/08/00</b>	ConCal:	<b>TB00750</b>
		Date Analyzed:	<b>02/15/00</b>		
Sample Size:	<b>10.000 g</b>	Dilution Factor:	<b>n/a</b>	% Moisture:	<b>0.1</b>
Dry Weight:	<b>9.990 g</b>	Blank File:	<b>T000757</b>	% Lipid:	<b>n/a</b>
GC Column:	<b>DB-5</b>	Analyst:	<b>JMM</b>	% Solids:	<b>99.9</b>

Analytes	Conc. (ng/kg)	DL	Ratio	RT	RRT	Flags
2,3,7,8-TCDD	ND	0.1				—
1,2,3,7,8-PeCDD	ND	0.2				—
1,2,3,4,7,8-HxCDD	ND	0.3				—
1,2,3,6,7,8-HxCDD	ND	0.3				—
1,2,3,7,8,9-HxCDD	ND	0.3				—
1,2,3,4,6,7,8-HpCDD	ND	0.6				—
1,2,3,4,6,7,8,9-OCDD	ND	1.2				—
2,3,7,8-TCDF	ND	0.1				—
1,2,3,7,8-PeCDF	ND	0.1				—
2,3,4,7,8-PeCDF	ND	0.2				—
1,2,3,4,7,8-HxCDF	ND	0.2				—
1,2,3,6,7,8-HxCDF	ND	0.2				—
2,3,4,6,7,8-HxCDF	ND	0.2				—
1,2,3,7,8,9-HxCDF	ND	0.3				—
1,2,3,4,6,7,8-HpCDF	ND	0.4				—
1,2,3,4,7,8,9-HpCDF	ND	0.6				—
1,2,3,4,6,7,8,9-OCDF	ND	1.0				—

Totals	Conc. (ng/kg)	Number	DL	Flags
Total TCDD	ND		0.1	—
Total PeCDD	ND		0.2	—
Total HxCDD	ND		0.3	—
Total HpCDD	ND		0.6	—
Total TCDF	ND		0.4	—
Total PeCDF	ND		0.2	—
Total HxCDF	ND		0.2	—
Total HpCDF	ND		0.5	—

# Franklin Industrial Minerals

TLI Project: **50114r3**  
 Client Sample: **50616L**

1613, Revision B PCDD/PCDF Analysis (c)  
 Analysis File: **T000759**

Client Project:	<b>Dioxin In Powdered Limestone</b>			Spike File:	<b>SP161B2S</b>
Sample Matrix:	<b>SOLID</b>	Date Received:	<b>12/10/99</b>	ICal:	<b>TF5911B</b>
TLI ID:	<b>252-25-2</b>	Date Extracted:	<b>02/08/00</b>	ConCal:	<b>TB00750</b>
		Date Analyzed:	<b>02/15/00</b>		
Sample Size:	<b>10.000 g</b>	Dilution Factor:	<b>n/a</b>	% Moisture:	<b>0.1</b>
Dry Weight:	<b>9.990 g</b>	Blank File:	<b>T000757</b>	% Lipid:	<b>n/a</b>
GC Column:	<b>DB-5</b>	Analyst:	<b>JMM</b>	% Solids:	<b>99.9</b>

Analytes	Conc. (ng/kg)	DL	Ratio	RT	RRT	Flags
2,3,7,8-TCDD	ND	0.1				—
1,2,3,7,8-PeCDD	ND	0.2				—
1,2,3,4,7,8-HxCDD	ND	0.3				—
1,2,3,6,7,8-HxCDD	ND	0.3				—
1,2,3,7,8,9-HxCDD	ND	0.3				—
1,2,3,4,6,7,8-HpCDD	ND	0.6				—
1,2,3,4,6,7,8,9-OCDD	ND	1.4				—
2,3,7,8-TCDF	ND	0.1				—
1,2,3,7,8-PeCDF	ND	0.1				—
2,3,4,7,8-PeCDF	ND	0.2				—
1,2,3,4,7,8-HxCDF	ND	0.2				—
1,2,3,6,7,8-HxCDF	ND	0.2				—
2,3,4,6,7,8-HxCDF	ND	0.2				—
1,2,3,7,8,9-HxCDF	ND	0.3				—
1,2,3,4,6,7,8-HpCDF	ND	0.4				—
1,2,3,4,7,8,9-HpCDF	ND	0.7				—
1,2,3,4,6,7,8,9-OCDF	ND	1.2				—

Totals	Conc. (ng/kg)	Number	DL	Flags
Total TCDD	ND		0.1	—
Total PeCDD	ND		0.2	—
Total HxCDD	ND		0.3	—
Total HpCDD	ND		0.6	—
Total TCDF	ND		0.3	—
Total PeCDF	ND		0.1	—
Total HxCDF	ND		0.2	—
Total HpCDF	ND		0.5	—

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